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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,827	05/03/2005	Michael Birsha Davies	P33145USW	4175
23347 GLAXOSMITI	7590 11/21/200 HKLINE	7	EXAM	INER
	INTELLECTUAL PRODR., PO BOX 13398	OPERTY, MAI B475	DIXON, ANNETTE FREDRICKA	
	RIANGLE PARK, NC	ADTIBUT ANDROUGH		PAPER NUMBER
			3771	
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			NOTIFICATION DATE	DELIVERY MODE
			11/21/2007	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM ROSALIE.M.CHAMBERLAIN@GSK.COM JULIE.D.MCFALLS@GSK.COM

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	Application No.	Applicant(s)	· · · · · · · · · · · · · · · · · · ·
	10/533,827	DAVIES ET AL.	
Office Action Summary	Examiner	Art Unit	
•	Annette F. Dixon	3771	
The MAILING DATE of this communication ap	pears on the cover sheet with	the correspondence address	<del></del>
Period for Reply	VIO CET TO EVOIDE A MC	MITHON OR THIRTY (20) DAY	VO.
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC. 136(a). In no event, however, may a rep will apply and will expire SIX (6) MONT e, cause the application to become ABA	ATION.  Ny be timely filed  HS from the mailing date of this communic NDONED (35 U.S.C. § 133).	
Status			
Responsive to communication(s) filed on 21 S     This action is <b>FINAL</b> . 2b)☑ This     Since this application is in condition for allowed closed in accordance with the practice under	s action is non-final. ance except for formal matte		ts is
Disposition of Claims			•
4) ☐ Claim(s) 1-33 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-33 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	awn from consideration.		
Application Papers			
9) The specification is objected to by the Examin	er.		
10) ☐ The drawing(s) filed on is/are: a) ☐ acc	· ·		
Applicant may not request that any objection to the		· .	21(4)
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E			
Priority under 35 U.S.C. § 119		·	
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat * See the attached detailed Office action for a list	nts have been received. Its have been received in Appority documents have been reau (PCT Rule 17.2(a)).	plication No eceived in this National Stage	<b>;</b>
Attachment(s)	_		
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)		/Mail Date	
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5)  Notice of Inf 6) Other:	ormal Patent Application -	

Application/Control Number: 10/533,827

Art Unit: 3771

### **DETAILED ACTION**

- 1. This Office Action is in response to the amendment filed on September 21, 2007. Examiner acknowledges claims 1-33 are pending in this application with claim 11 having been currently amended.
- 2. Examiner apologies for any inconvenience incurred by the Attorney and the Applicant to make this Office Action a second non-final rejection. Examiner is more than willing to expedite prosecution by a personal or telephonic interview.

### Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 1-4, 11, 15, 19-21, 24, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor (6,029,659).

As to Claim 1, O'Connor discloses a holder (10) for dispensing a dispensing container system (11) which is adapted to dispense a quantity of fluid contained therein on movement thereof relative to the holder and further inclues a dispensing counter means (40) for counting the number of quantities of the fluid dispensed, the holder having a moulded plastics body with inner and outer surfaces, the inner surface bounding a cavity adapted to receive the dispensing container system (11) in movable relation thereto, the cavity having moulded counter advance means (50) adapted in use

Application/Control Number: 10/533,827

Art Unit: 3771

to cooperate with the dispensing counter means (40) on relative movement between the dispensing container system (11) and the body (10) to advance the dispensing counter means (40) to indicate the dispensing of a quantity of the fluid, wherein the body (10) is formed with an outlet port (12) in communication with the cavity such that the fluid dispensed from the dispensing container system (11) is dischargeable therethrough, and wherein an aperture (60) extends through the body (10) from the outer surface to the inner surface in alignment with the counter advance means (40). (Figure 5).

As to Claims 2-4, 11, 15, 19-21, 24, and 30, O'Connor discloses the recited particulars of the counter and advance means, wherein the counter (40) and the ratchet elements of the advance means (50) are utilized to actuate the medicament to the patient and advise the patient of the amount of medicament remaining. (Figure 5).

# Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 5-10, 12-14, 16-18, 23, 25-29, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor (6,029,659) in view of Rand et al. (WO 98/56444).

As to Claims 5-10, 12, and 23, O'Connor discloses the holder for the dispensing container system, yet odes not expressly disclose the orientations of the dispensing

Application/Control Number: 10/533,827

Art Unit: 3771

container system. However, at the time the invention was made the use of the structural orientations was known. Specifically, Rand teaches the use of the structural orientations to prevent the rotation of the dispensing container (11). (Figure 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Connor to include the retaining means, as taught by Rand to prevent rotation of the dispensing container system within the housing.

As to Claims 13, 14, and 16-18, Rand discloses the outlet port of the holder forms a nozzle for insertion into the nose of a patient (Page 8, Lines 8-11).

As to Claims 22 and 33, Rand disclose a holder for an inhaler comprising all the recited elements, yet does not expressly disclose the use of injection molding.

However, at the time the invention was made the use of injection molding in the formation of inhalers was well known for the ability to enable the uniform construction of the device thereby lowering the costs associated with manufacture. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construction the holder for the inhaler via injection molding as this process enabling higher product production as the Applicant has done.

As to Claims 25-29, 31, and 32, Rand discloses the container (2) has an outlet member (6) and a container member (the region holding the medicament) which contains the fluid and is movable relative to the outlet member to dispense fluid from the outlet member. Further Rand discloses the use of stand (10) to support the container (2) in operation.

Art Unit: 3771

## Response to Arguments

7. Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-27/2-1000-

Annette F Dixon Examiner

Art Unit 3771

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

11/14107